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Analysis on Effect of Jinshuibao Capsule Combined Treatment on Newly Diagnosed Pulmonary Tuberculosis

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ABSTRACT Objective: To discuss the clinical effect of jinshuibao capsule combined treatment on newly diagnosed pulmonary tuberculosis. **Method:** 62 cases of newly diagnosed pulmonary tuberculosis patients, who were treated in our hospital from January 2013 to January 2014, were served as the object of study. They were randomly divided into control group and treatment group. Patients in the control group received a single 2SHRZ/4HR chemotherapy, while the treatment group received jinshuibao capsule combined treatment on the base of control group. The improvement of clinical symptoms, chest X-ray film and laboratory examination results of both groups were compared and analysed. **Results:** The total effective rate of clinical treatment, lesion absorption, sputum negative conversion and improvement rate of clinical symptom of treatment group was obviously better than the control group. The difference of clinical effect between two groups was statistically significant ($p < 0.05$). **Conclusion:** Jinshuibao capsule combined treatment has satisfactory clinical effect on newly diagnosed pulmonary tuberculosis.

KEYWORDS

Jinshuibao capsule
Combined treatment
Newly diagnosed pulmonary tuberculosis

1. Introduction

Tuberculosis is a chronic infectious disease, which is seriously harmful to human health. Jinshuibao capsule is a kind of clinical drugs, which is commonly used to protect liver, kidney and other organs. The clinical effect of Jinshuibao capsule combined treatment on newly diagnosed pulmonary tuberculosis was analyzed in this paper. The results are reported as follow.

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2. Materials and methods

2.1. Clinical data

62 cases of newly diagnosed pulmonary tuberculosis patients, who were treated in our hospital from January 2013 to January 2014, were served as the object of study. All the patients were diagnosed as pulmonary tuberculosis by clinical examination, conformed to the diagnostic criteria developed by National tuberculosis prevention and control work academic conference in 1982. Their hospitalization time was above two months. The patients were divided into control group and treatment group randomly, 31 cases in each group. Among them, the control group had 16 males and 15 females, the patient's age was ranged from 18 to 72 years old, with the mean of (44.5 ± 15.4) years old, there were 9 cases of V pulmonary tuberculosis, 31 cases of III pulmonary tuberculosis and 1 case of II pulmonary tuberculosis. The treatment group had 15 males and 16 females, the patient's age were ranged from 20 to

70 years old, and the mean was (46.5 ± 11.5) years old, there were 9 cases of V pulmonary tuberculosis, 30 cases of III pulmonary tuberculosis, 2 cases of II pulmonary tuberculosis. There was no statistical difference in clinical data between two groups ($p > 0.05$).

2.2. Methods

Both groups were treated with 2SHRZ/4HR chemotherapy. For patients with S allergies, E treatment was given, that was, patients were treated with pyrazinamide Z, rifampicin R, isoniazid H and streptomycin S during the first two months of treatment, followed by ethambutol E in the later four months. Usage and dosage of drug in the two schemes are the same. On this basis, the treatment group received oral treatment of Jinshuibao capsule, produced by Jiangxi Jinshuibao Pharmaceutical Co., Ltd, 5 capsules each time, 3 times a day after each meal.

2.3. Observation index

Firstly, chest X-ray film was conducted to inspect lesions absorption of patients. Lesions absorption referred to that the chest X-ray film examination confirmed that the lesion cavity was closed or the absorption rate of more than 50%. Secondly, improvement of clinical symptoms of patients was observed, such as anorexia, cough, night sweats, fever and other symptoms. Thirdly, sputum negative conversion situation of both groups was examined [1]. Fourthly, the total effective rate of clinical treatment of patients in both groups was determined. Cure referred to there was no active lesions found on chest X-ray film after clinical treatment, sputum negative conversion time was more than one year, related clinical symptoms completely disappeared and the lesion was relatively stable after one year of follow-up. Improvement implied that the lesion was significantly reduced or the cavity was closed after the clinical treatment, result of sputum test was negative and the related clinical symptoms disappeared. Invalid indicated that there was no change in the results of chest X-ray and sputum test after clinical treatment. Total Effective Rate = (Cure + Improvement) / Total of Cases × 100% [2].

2.4. Statistical treatment

The medical research data were statistically analyzed by SPSS 17.0 software. (x ± s) was used to express the measurement data, a comparative analysis of the data was made by single factor analysis of variance, and use X^2 test to do statistical analysis on count data, if $p < 0.05$, the difference between data is statistically significant [3].

3. Results

After one month of clinical treatment, in the treatment group, the improvement rate of symptoms such as cough, expectoration, anorexia, fatigue, night sweats, low-grade fever and other symptoms was 80%. After 3 months of treatment, the improvement rate of clinical symptom was 100%. While in the control group, after one month of clinical treatment, the improvement rate of symptoms such as cough, expectoration, anorexia, fatigue, night sweats, low-grade fever and other symptoms was 50%. After 3 months of treatment, the improvement rate was 80%. There was statistical difference in the improvement rate of symptoms between two groups ($p < 0.05$). For the sputum negative conversion rate, after one, three and six months of clinical treatment, the value in the treatment group was 50%, 70% and 90% respectively; while the value in the control group was 20%, 50% and 70% respectively. There was statistical difference in the sputum negative conversion rate between two groups ($p < 0.05$). The absorption rate of lesions was 94% in the treatment group, while the absorption rate of lesions was 74% in the control group. There was statistical difference in the absorption rate of lesions between two groups ($p < 0.05$). In the treatment group, the total effective rate of clinical treatment was 96.77%; whereas in the control group, the total effective rate of clinical treatment was 41.91%. There was statistical difference in the total effective rate of clinical treatment between two groups ($p < 0.05$). The results were shown in Table 1.

4. Conclusions

When an individual is infected with Mycobacterium tuberculosis, immunity is an important factor to determine the occurrence and development of tuberculosis. Cell immunity that mediated by T lymphocyte is mainly responsible for tuberculosis immunity. Furthermore, humoral immunity also plays a certain role. The study showed that patients with pulmonary tuberculosis will have an abnormal cellular immune function, CD 4^+ T lymphocyte decreased, CD 8^+ T lymphocyte increased, CD 4^+/ CD 8^+ ratio decreased or even inverted. In fact, NK cells can optimize CD 8^+ T cells to produce 7-interferon and engulf cells that are infected with *Mycobacterium*

Table 1. Comparison and analysis of clinical effects between two groups of patients with pulmonary tuberculosis (n%).

Group	Case (n)	Cure	Improvement	Invalid	Total Effective Rate
Treatment group	31	29 (93.55%)	1 (3.23%)	1 (3.23%)	30 (96.77%)
Control group	31	12 (38.71%)	1 (3.23%)	18 (58.06)	13 (41.91%)
χ^2	/	4.36	/	12.18	4.08
P value	/	<0.05	/	<0.05	<0.05

tuberculosis, thus, playing a key role in innate immunity against TB [4,5]. Also, B cells can reduce the inflammatory response in patients with pulmonary tuberculosis and enhance the containment of *Mycobacterium tuberculosis*. In the research, there was no difference in the levels of B cells, NK cells, CD 4^+, CD 8^+ and CD 4^+/CD 8^+ between two groups before treatment. After application of Jinshuibao capsule, compared with the control group, B cells, NK cells and CD 4^+ levels of the treatment group were elevated, CD 8^+ level decreased, CD 4^+/CD 8^+ elevated. Hence, Jinshuibao capsule can improve the cellular immune function of patients with pulmonary tuberculosis. The CD 4^+ cells was decreased, the function producing lymph nodes, stimulating B cells to produce IgG, IgA, IgM antibody and helping other lymphocytes weaken, suggesting that the immune function is low. The decrease of CD 4 cells that resulted from the weakening of cellular immunity of patients with pulmonary tuberculosis would affect the level of IgM, IgA and IgG [6]. However, some scholars believe that the level of humoral immunity in tuberculosis patients is elevated, playing a role in the immune process of pulmonary tuberculosis.

Jinshuibao capsule is a kind of drug, which is produced artificially by isolation from aweto, followed by fermentation and purification process.. The main chemical components include 19 amino acid, such as mannitol, uracil, adenine, adenosine, etc. Besides, it is composed of variety of vitamins, selenium, zinc and other trace elements. The satisfactory clinical effect of Jinshuibao capsule in treatment of newly diagnosed pulmonary tuberculosis is mainly attributed to several drug action mechanisms. Firstly, it helps to improve the tolerance of patients to drug chemotherapy, improve the adverse reactions symptoms, provide protective effects on the function of important organs such as liver and kidney, reduce DNA damage, gives protective effects on the function and structure of cell membrane, prevent calcium influx and improve the lipid metabolism of cell membrane. Jinshuibao capsule gives similar detoxification effect as other types of drugs, especially for anti-tumor drugs. Secondly, it can improve phagocytic ability of macrophage-monocyte system, protect cellular immunity. Patients with pulmonary tuberculosis will have varying degree of decreased cellular immunity. Although the conventional BCG, transfer factor and levamisole give certain curative effect, treatment cost and incidence of adverse reactions after the treatment are much higher. So, the clinical application is limited. Meanwhile, the killing ability of Jinshuibao capsule on *Mycobacterium tuberculosis* and phagocytic ability on macrophage is strong. Moreover, there is no obvious toxic side effect and the cost of treatment is lower. Therefore, patients are readily to accept, making higher clinical application value. Thirdly, in addition to the conventional effects of anti-asthmatic, expectorant and antitussive, Jinshuibao capsule gives the effects of strong nourishing, hypnotic and sedative as well as the ability of regulating and improving the body's energy metabolism, consequently prompting the body recovery and effectively controlling the clinical symptoms.

Domestic studies prove that cytokines might be involved in the immune response of tuberculosis. TNF-α is produced by monocytes, macrophages and lymphocytes, which promote macrophage activation, thus enhancing its phagocytosis. Also, it is involved in the formation of granuloma and it can play a protective role in *Mycobacterium tuberculosis* infection. IFN-γ is an immune regulatory factor secreted by Th1 cells. It can activate monocytes and control the spread of infection. At the same time, it enhances the bactericidal effect of macrophages, plays an important role in anti-tuberculosis immunity. sIL-2R is a kind of important immune inhibitory substance. It can inhibit the proliferation of T cells, weaken the immune response of IL-2, causing NK cell, which is an effector cell of IL-2, difficult to maintain its natural killer activity. IL-10 acts as a suppressor cell factor, if it is over secreted, chronic and recurrent *Mycobacterium tuberculosis* infection could be promoted [7].

In conclusion, Jinshuibao capsule combined therapy has satisfactory clinical effect on newly diagnosed pulmonary tuberculosis, lower adverse reactions and higher control rate of clinical symptom. Hence, it provides high clinical application value.

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